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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,849	10/29/2003	Jerome David	SPINE 3.0-414	7827
530	7590	01/30/2007	EXAMINER	
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			SWIGER III, JAMES L	
			ART UNIT	PAPER NUMBER
			3733	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/30/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/695,849	DAVID, JEROME	
	Examiner	Art Unit	
	James L. Swiger	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 October 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-31 and 39-42 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-31 and 39-42 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 29 October 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/19/2006</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

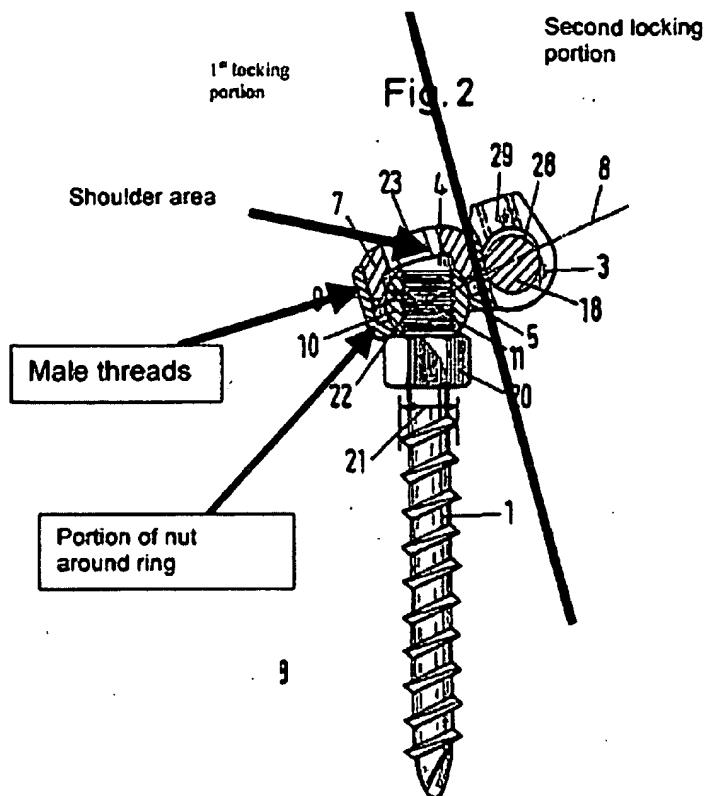
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Studer et al. (US 6,146,383). Studer et al. discloses a bone fixation assembly comprising what is considered a unitary coupling element (see element in Fig. 2) that permits axial and sliding movement (9) of the coupling element (1) relative to the fixation element (Figs. 1 vs. 2), and that is also adapted to receive a spinal rod (18). The bone fixation assembly also has a first locking element to secure the head portion in the first bore and a second locking element adapted to secure the spinal rod in the second bore. See drawing below.



The coupling element also comprises a locking nut (7) in the first portion, and where the first locking element comprises a ball ring (9). The second bore via the spinal rod would therefore also have an axis that is transverse to the first bore, extending coplanar in the transverse direction. Further, once the second locking element (through bore 29, and would be considered as a set screw (24)) is set into the device, it is capable of being permanent if the user chooses it to be, and would be fully secure in the connection and stabilizing the spinal rod in place. The device further comprises male threads in the first bore (see drawing above) and wherein at least a portion of the locking nut surrounds the ball ring. The male threads would inherently fit into the female threads provided on the side of the first bore. The ball ring (9) is also in contact with the coupling member portion (5) at the bottom end of the ring, and the locking nut (7) at the

top. The second locking assembly also comprises a set screw (24) that is capable of being seated in the locking member if the user wishes it to be. Also, the bottom portion of the ball ring (9) is tapered (see bottom portion of the first locking element in drawing above) to allow poly-axial motion. The fixation element also has a head portion (proximate to 22) that fits into the first locking element. Further, the ball ring and the locking nut associate with each other and with the head portion of the fixation element that is capable of exerting a radial force onto that element to secure the head of the screw in the coupling element. The set screw (24) or locking nut (7) may provide this means for providing radial forces.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

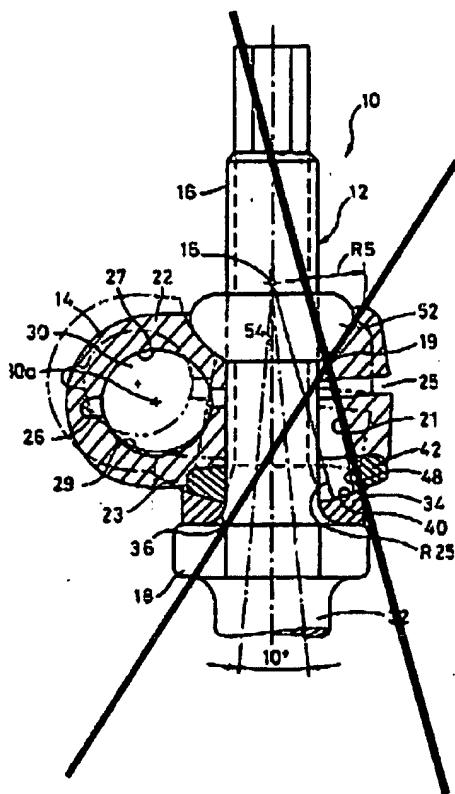
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 8-16, 19-31, and 39-42 rejected under 35 U.S.C. 103(a) as being unpatentable over Studer et al. '383 in view of Schlapfer et al. (US Patent 5,501,684). Studer et al. disclose the claimed invention except for a ball ring or coupling element to be *slidably* fixed. Schlapfer et al. disclose a coupling element (2) that is capable of slidably moving with respect to the fixation element in the device so that it can be properly adjusted before being secured (see also Col. 4, lines 41-57). It would have

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been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Studer et al. having at least a coupling element or ball ring that moves slidably with respect to a fixation element in view of Schlapfer et al. to better use and orient the device for fixation of the bone.

Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Studer et al. '383 and Schlapfer et al. '684, as applied to claim 16 above, and further in view of Lange (US Patent 6,123,706). The combination of Studer et al. '383 and Schlapfer et al. '684 disclose the claimed invention except for a taper in the locking nut extending in opposite directions from that of the bore. Lange discloses a taper that is considered to go in opposing directions from the bore and to the locking nut area. See drawing below.



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The lines above represent the two tapers: one from the locking nut area (upper portion) and one from the bore (lower portion). These tapers provide a means for the spinal screws to be readily adjusted when they are in use. (See Col. 1, lines 35-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the bone fixation device of the combination of Studer et al. and Schlapfer et al. having at least opposing tapers in view of Lange to better allow the spinal fixation element to be adjusted in use.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Studer et al. '383 in view of Gu et al. (US 6,280,443). Studer et al. disclose the claimed invention except for a flared lip that cooperates with the coupling element. Gu et al discloses a taper (see drawing below) that allows for the set member bore (32) to better secure to the rod (Col. 4, lines 42-58).

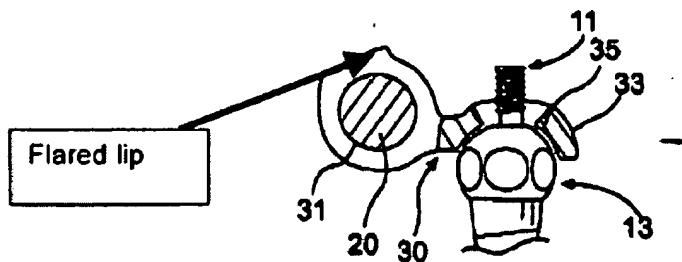


FIG. 4A

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the spinal fixation device of Studer et al. having at least a flared lip in view of Gu et al. to better secure the locking element and the rod in place and prevent the locking element from becoming removed.

Response to Arguments

Applicant's arguments filed 10/30/2006 have been fully considered but they are not persuasive. With regards to applicant's arguments regarding that claim 1 previously contained language regarding the sliding movement, the examiner asserts that the claim was interpreted that the coupling element (9) slides with respect to the fixation element, interpreted as the entire device of Fig. 1 versus Fig. 2.

Otherwise, Applicant's arguments with respect to claims 1-42 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

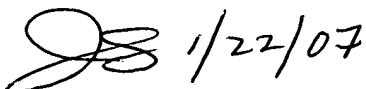
Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-

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5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



JLS



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER